

REMARKS

The foregoing amendment is submitted to more clearly set forth the claimed invention and to highlight the differences between the claimed invention and the
5 cited prior art.

The invention is now characterized as a device which includes three principal components. The first component is a substrate for supporting a complement to the substance to be detected. The second component is the indicating agent, which
10 generates a desired detectable fluorescent signal operatively associated with the substance in the sample, whereby the binding of the substance in the sample to the complement results in the fixing of the indicating agent to the complement on the substrate in a manner wherein the detectable fluorescent signal is generated. The third component is a protective coating. The protective coating is affixed to the device
15 including during the assay and covers the indicating agent fixed to the complement to protect the same from the ambient environment.

In particular, the protective coating is comprised of a protective coating forming material which is impervious to the penetration of at least one gas which is capable of
20 adversely affecting the indicating agent. In addition, the protective coating does not itself generate an adverse amount of undesired signals and furthermore is at least substantially transparent to any excitation wavelength necessary to excite the

indicating agent as well as the desired detectable signal generated by the indicating agent. The device is suitable for use in an assay for the detection of substance in a sample suspected of containing the same.

5 Thus, claim 1 focuses on the device suitable for use in an assay in which the substrate, indicating agent and protective coating are the principle components thereof.

Support for the description of the substrate and the indicating agent as now set forth in amended claim 1 is found throughout the specification and furthermore is
10 commonly employed in most type of assays. Initially, an indicating agent is attached to the substance in the sample in preparation for analysis. The substrate is prepared supporting thereon a complement having a specific affinity for the substance in the sample. The sample is introduced to the substrate. The substance along with the attached indicating agent, binds to the complement. This binding yields a positive
15 outcome in the form of a detectable fluorescent signal. To preserve and extend the life of the indicating agent fixed to the complement, a protective coating is then applied to cover the indicating agent. This aspect of the device is apparent from the examples, and particularly Example 1 starting on page 16 describing the preparation of a microarray substrate (i.e. an example of the device suitable for use in an assay) and the
20 testing of the protective coating, and from the Specification at page 3, line 22 to page 4, line 11, and at page 5, line 5 to page 6, line 9.

Claims 1, 3-5, and 29-33 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Office Action advises that the "original specification does not explicitly state the cover is permanently affixed as presently claimed." Applicants have amended claim 1 to delete the term 5 "permanently" to satisfy the written description requirement. Withdrawal of the rejection under 35 U.S.C. Section 112 is therefore deemed proper and is respectfully requested.

Claims 1, 3-5 and 29-33 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject 10 matter which applicant regards as the invention. The Office Action advises that the "instant language emphasizes the protective coating is not removed when the device is exposed to the sample...it is not clear how the sample interacts with the reagent through the protective coating." The Office Action further advises that "claim 29 is not clear what structure is intended by an 'array substrate'." The language of claim 1 as now 15 presented more clearly characterizes all the features of the present invention. Withdrawal of the rejection under 35 U.S.C. Section 112 is therefore deemed proper and is respectfully requested.

With regard to claim 29, Applicants have canceled claim 29. Withdrawal of the 20 rejection under 35 U.S.C. Section 112 is therefore deemed proper and is respectfully requested.

Claims 1, 3-5, and 29-33 stand “rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tomita et al. (USP 4,829,187).” This rejection is hereby traversed and reconsideration is respectfully requested.

5 Tomita et al. (U.S. 4,829,187) disclose a UV-ray sensitive composition and element for measuring UV-ray dose in which the element includes a “layer (2) containing a photoactivator, a discoloring agent, etc, to provide a colorimetric response” is said in the Office Action to read on the “indicating agent” of the present invention. This is not the case.

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Tomita et al. teach at Col. 5, lines 27-30 and Col. 5, line 67 to Col. 6, line 3, that that the layer (2) contains a photoactivator forming a free radical upon exposure to UV-ray irradiation, and a discoloring agent which exhibits a color change upon reaction with the formed free radical. This is materially different to what is claimed by Applicants.

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In the present invention, the indicating agent is operatively associated with the substance in the sample, whereby the binding of the substance in the sample to the complement results in the fixing of the indicating agent to the complement on the substrate in a manner wherein the detectable fluorescent signal is generated.

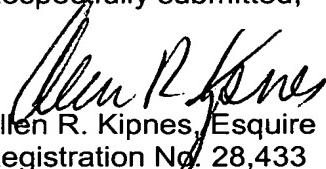
20 Accordingly, the claimed invention is neither anticipated by nor rendered obvious over Tomita et al.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and respectfully requested.

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It is believed that all the requisite fees are enclosed herewith. However, if any additional fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,



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